

REMARKS/ARGUMENTS

Claims 1 through 3 and 18 have been withdrawn in view of a previous Restriction Requirement. Applicants affirm that the election of Group II, claims 4-17, drawn to a soft gel capsule.

Claims 4 through 17 are presently pending.

Claims 4, 7-11, 13, 14 and 17 have been amended to more particularly point out and distinctly claim the invention.

No new subject matter has been added.

Rejection of Claims 4-17 under 35 U.S.C. § 112, Second Paragraph

Claims 4-17 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter, which applicants regard as the invention.

Claim 4 was made indefinite by the word “and”. The Office Action suggested that the word “and” be replaced by the word “for”. Claim 4 has been amended to include the word “for”, thereby obviating the basis for this rejection. Reconsideration and withdrawal of the rejection is respectfully requested.

Claim 4 stood rejected for the phrase “maintenance of blood sugar levels”. The phrase “maintenance of blood sugar levels” has been deleted and replaced with “maintaining or lowering blood sugar levels”.

Support for the phrase “maintaining or lowering blood sugar levels” and the amendment can be found in the specification at, for example, page 7 lines 8 through 14 that states:

Therefore, oral formulations of leaf extract of
Lagerstroemia speciosa L. standardized to 1% Corosolic acid
(Glucosol™) exert a marked lowering of blood sugar in type 2

diabetics and also a significant and sustained weight –loss without any adverse effects. Further, the results of this study indicate that Glucosol™ does not alter either the absorption or clearance of blood sugar in non-diabetic subjects, while retaining its weight-loss effect. (Referring to page 6, line 10 through page 7, line 7.)

Hence, blood sugar levels and be lowered or, in non-diabetic subjects, maintained. Applicants consider that the new phrase obviates the pending rejection and respectfully requests reconsideration and withdrawal of the rejection.

Claims 4, 7-11, 13, 14 and 17 stand rejected as being vague and indefinite by the term “including”.

Claims 4, 7-11, 13, 14 and 17 have been amended to replace the word “including” with the word “comprising” as suggested in the Office Action, thereby obviating the basis for the rejection. Reconsideration and withdrawal of the rejection is respectfully requested.

Rejection of Claims 4-6, 12, 15 and 16 under 35 U.S.C. § 103(a)

Claims 4-6, 12, 15 and 16 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Matsuyama (US Patent No. 6,485,760, hereinafter “Matsuyama”) in view of Hoffman (The Complete Illustrated Herbal, *Practical Herbalism, The Preparation of Herbs*, 1996, pages 20-33, hereinafter “Hoffman”). Applicants respectfully traverse this rejection for at least the following reasons.

Matsuyama discloses an oral composition, a hard “tablet” (See column 5, line 50 through column 6, line 20) for an increase in lowering of blood sugar levels in a patient with a powered herbal extract containing corosolic acid. As the Office Action notes, Matsuyama fails to teach or suggest in any of its disclosure that anything but a tablet could be used with the corosolic acid. Furthermore, Matsuyama fails to provide any motivation or an expectation of success that a corosolic concentrate could be formulated into anything but a tablet.

Hoffman, is a general teaching that dried herbs can be placed into a *two-piece* gelatin capsule. As Hoffman shows at page 26, these are “*hard*” gelatin capsules that come in *two*

pieces. The powdered herbs must be placed into the two halves. One half of the capsule has a larger circumference than the second one half of the capsule. The two halves are pushed together with the larger half sliding over the smaller half, to form a seal and the two-piece capsule. There is a definitive contact line formed between the two halves when the capsule is completed. This seal, or contact line, can cause discomfort to a patient because of the rough edge formed at the seal.

The basis of the Office Action fails to appreciate that the current claims are directed to a “soft gel capsule”. A soft gel capsule is a unitary capsule. That is, there is no “seal”, “contact line” or rough edge because there are no two distinct halves for forming. A soft gel capsule thus provides a unitary capsule that contains a product, such as corosolic acid. This unitary soft gel provides the patient with the advantage of easier swallowing due to a lack of a seal, contact line or rough edge.

Therefore, Hoffman does not teach or suggest, provide any motivation or an expectation of success such that one having ordinary skill in the art would seek to prepare a unitary “soft gel capsule” that contains any herb, lest corosolic acid. Hoffman merely teaches two-piece capsules.

In fact, if Matsuyama and Hoffman were combined, the result would be a *two-piece hard gelatin capsule* that contains powdered corosolic acid extract. This is not equivalent to that of the currently claimed subject matter.

Consequently, Matsuyama and Hoffman, alone or in combination, do not teach or suggest, provide any motivation or an expectation of success to one having ordinary skill in the art that a unitary “soft gel capsule” containing corosolic acid could be prepared.

Reconsideration and withdrawal of the rejection is respectfully requested.

Rejection of Claims 4-17 under 35 U.S.C. § 103(a)

Claims 4-17 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Matsuyama in view of Hoffman, US Patent No. 6,303,586 (hereinafter “McPeak et al.”), US

Patent No. 6,407,068 (hereinafter “LaGrone”), US Patent No. 5,552,427 (hereinafter “Matsutani et al.”) and US Patent No. 5,980,902 (hereinafter “Shanmuyasundam et al.”). Applicants respectfully traverse the rejection for at least the following reasons.

Matsuyama and Hoffman have been discussed in the previous section. The arguments presented therein are reiterated and incorporated here in their entirety.

The Office Actions states that McPeak et al. teach the use of rice bran oil to control blood glucose levels. This is not correct. McPeak et al. teach the use of *rice bran derivatives* that are solids/powders and *not an oil* to treat blood glucose levels.

McPeak et al. fail to teach or suggest the use of a soft gel capsule. As stated above, McPeak et al. fail to teach or suggest the use of rice bran *oil* in any application. McPeak et al. do not teach or suggest the use of rice bran *oil* in combination with corosolic acid in a soft gel capsule

McPeak et al. fail to remedy the deficiencies of Matsuyama and Hoffman, alone or in combination. None of the references, alone or in combination teach or suggest, provide any motivation or an expectation of success to one having ordinary skill in the art that a unitary “soft gel capsule” containing corosolic acid could be prepared, let alone a soft gel capsule with rice bran oil incorporated into the capsule.

The combination of these references, would at best provide a *two-piece hard gelatin capsule* that contains powdered corosolic acid extract and a powdered rice bran derivative, not rice bran oil. The result is not the presently claimed invention.

Reconsideration and withdrawal of this rejection is respectfully requested.

LaGrone teaches the use of silica to prevent diabetes.

LaGrone does not teach or suggest the use of silica in a soft gel capsule. Furthermore, LaGrone does not teach or suggest the use of silica in combination with corosolic acid in a soft gel capsule.

LaGrone fails to remedy the deficiencies of Matsuyama and Hoffman, alone or in combination. None of the references, alone or in combination teach or suggest, provide any motivation or an expectation of success to one having ordinary skill in the art that a unitary “soft gel capsule” containing corosolic acid could be prepared, let alone one with silica incorporated into the capsule.

The combination of these references, would at best provide a *two-piece hard gelatin capsule* that contains powdered corosolic acid extract and a powdered rice bran derivative, not rice bran oil and/or silica. The result is not the subject matter of the present invention..

Reconsideration and withdrawal of this rejection is respectfully requested.

Shanmuyasundam et al. disclose an extract of *Gymnema sylvestre* is useful for inhibiting glucose absorption thereby preventing obesity.

Shanmuyasundam et al. do not teach or suggest the use of *Gymnema sylvestre* in a soft gel capsule. Shanmuyasundam et al. do not teach or suggest the use of *Gymnema sylvestre* in combination with corosolic acid in a soft gel capsule

With regard to claim 17 in particular, Shanmuyasundam et al. fail to remedy the deficiencies of either Matsuyama or Hoffman, alone or in combination. None of the references, alone or in combination teach or suggest, provide any motivation or an expectation of success to one having ordinary skill in the art that a unitary “soft gel capsule” containing corosolic acid could be prepared, let alone one with *Gymnema sylvestre* incorporated into the capsule.

The combination of these references, would at best provide a *two-piece hard gelatin capsule* that contains powdered corosolic acid extract and a powdered *Gymnema sylvestre* extract, which is not the subject matter of the present invention..

Reconsideration and withdrawal of this rejection is respectfully requested.

Matsutani et al. disclose that *tablets* can be *polished* with bees wax to *coat* the tablet.

Matsutani et al. do not teach or suggest the use of bees wax with a soft gel capsule. Furthermore, Matsutani et al. do not teach or suggest the use of bees wax in combination with corosolic acid in a soft gel capsule.

Matsutani et al. fail to remedy the deficiencies of either Matsuyama or Hoffman alone or in combination. Matsutani et al. *coat* the *tablet* with bees wax. In contrast, the presently claimed subject matter incorporates the bees' wax within a *soft gel capsule*.

The combination of these references, would at best provide a *two-piece hard gelatin capsule* that contains powdered corosolic acid extract that has been polished with bees wax, which is not the subject matter of the present invention.

Reconsideration and withdrawal of this rejection is respectfully requested.

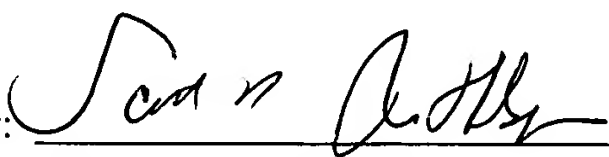
Conclusion

This application now stands in allowable form and reconsideration and allowance is respectfully requested. If a telephonic consultation would help to expedite the processing of the application, the Examiner is urged to contact the attorney below at the Examiner's convenience.

Respectfully submitted,

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